



NOBAMED Paul Danz AG

NOBAGAZE®

REF 270410

Product Description, Intended use, Application

The disposable product NOBAGAZE® is a bleached, double-layered, and stretchable bandage made of gauze with a **size of 10 cm x 4 m**. It is made of 100% cotton is airy, breathable and hypoallergenic. The gauze bandage is suitable for primary wound care and for the fixation of wound dressings. The material may be sterilized and is therefore applicable in operative areas, too. The special stretching properties of the material and the associated low elastic recovery force make it easy to apply without wrinkles and without exerting excessive pressure on the wound. NOBAGAZE® thus offers a high degree of wearing comfort for particularly pain-sensitive wounds (e.g. on the head). Due to the two-layer structure, an additional padding effect is achieved.

Composition

Cotton

Note

Must be sterilized with a validated sterilization process before use on open wounds (moist heat at 121°C/134°C, 2-3 bar, according to DIN EN 17665, by irradiation according to DIN EN ISO 11137, or by ethylene oxide according to DIN EN ISO 11135.).

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulatory Requirements, Common Standards

Medical device according to the MDD 93/42/EEC and MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging: folding box
 made of
 cellulose

Secondary packaging: carton made of
 cellulose

Symbols used in labelling

Explanations at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and DIN EN 1041.

Storage and Transport

To be stored in a dry and dust-free environment

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.